

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

**UNITED STATES OF AMERICA**

**v.**

**[1] THOMAS K. WEIR  
[3] WILLIAM L. DONALDSON  
[4] PAMELA SPIVEY**

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**Case No. 2:21-cr-00008  
Judge Aleta A. Trauger**

**MEMORANDUM**

Before the court is the Amended Motion to Dismiss Counts One–Six of the Indictment (Doc. No. 430), filed by defendants Thomas Weir, William Donaldson, and Pamela Spivey. For the reasons set forth herein, the motion will be denied.

**I. BACKGROUND**

The defendants in this case are the former owners of two pharmacies located in Celina, Clay County, Tennessee. (Indictment, Doc. No. 3 ¶¶ 15–16, 19, 23–25.) Defendant William Donaldson was also formerly the Pharmacist-in-Charge and a “patient recruiter” for one of the pharmacies. (*Id.* ¶¶ 18, 19.) Unindicted co-conspirators include individuals formerly employed at one or both pharmacies, some of whom are pharmacists. (*Id.* ¶¶ 20–22, 26–28.) The pharmacies, Dale Hollow Pharmacy and Xpress Pharmacy, were formed and registered under the laws of Tennessee and operated as retail pharmacies licensed with the Tennessee Board of Pharmacy. (*Id.* ¶¶ 15, 23.)<sup>1</sup>

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<sup>1</sup> Both pharmacies were shut down by a temporary restraining order and then preliminary injunction entered by this court in February 2019, and the civil case against them is still pending, having been stayed until after a verdict is reached in this case. *See United States v. Oakley Pharmacy, Inc.*, No. 2:19-cr-00009 (M.D. Tenn.), ECF Nos. 60, 69. Two of the pharmacists

On November 15, 2021, a Grand Jury returned an Indictment (Doc. No. 3), charging the three moving defendants and Charles Oakley<sup>2</sup> in seven counts: (1) conspiracy to violate the Controlled Substances Act (“CSA”), 21 U.S.C. § 841(a), by “knowingly and intentionally and without lawful authority” distributing Schedule II, III, and IV controlled substances without a legitimate medical purpose and outside the usual course of professional practice, all in violation of 21 U.S.C. § 846 (Count One); (2) conspiracy to engage in health care fraud, in violation of 18 U.S.C. § 1349 (Count Two); (3) health care fraud, in violation of 18 U.S.C. § 1347, against defendants Weir and Spivey only (Counts Three through Six); and (4) conspiracy to defraud the government and to violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), in violation of 18 U.S.C. § 371, against defendants Weir and Donaldson (Count Seven).<sup>3</sup> The misconduct alleged in the Indictment spans from 2014 through February 2019.

Defendant Weir, ultimately joined by the other defendants, filed his first Motion to Dismiss Indictment for Lack of Fair Notice in September 2023, arguing that the Indictment failed to sufficiently allege his culpable mental state, as required by *Ruan v. United States*, 597 U.S. 450 (2022), and, alternatively, that the claims charged against him were insufficiently specific. (Doc. No. 182.) The court denied the motion, finding that *Ruan* said nothing about the pleading requirements for charges under the CSA and, in any event, that the Indictment in this case clearly alleges the required *mens rea* and “set[s] forth the critical details of the offense[s] charged.” (Doc. No. 198 at 4 (quoting *United States v. Edington*, 526 F. App’x 584, 588 (6th Cir. 2013)).) In

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involved in the alleged conspiracy pleaded guilty to federal charges in 2021. *United States v. Polston*, No. 2:19-cr-00006 (M.D. Tenn. Mar. 23, 2021), ECF No. 63; *United States v. Griffith*, No. 2:21-cr-00002 (M.D. Tenn. Aug. 26, 2021), ECF No. 17.

<sup>2</sup> Charles Oakley pleaded guilty in January 2024. (Doc. No. 268.)

<sup>3</sup> The Motion to Dismiss does not challenge Count 7.

January 2024, the defendants jointly filed their Second Motion to Dismiss Indictment, this time alleging selective prosecution and arguing that it was “arbitrary, random, and unreasonable for the government to select [the defendants’ two pharmacies] for prosecution from a pool that included pharmacies obviously much more responsible for the opioid crisis” than the defendants’. (Doc. No. 275 at 3.) The court denied that motion as well, finding that, because the defendants did not allege that the prosecution had a discriminatory purpose or effect, a rational basis review of the Indictment applied, and, under that standard, the defendants failed to negate every conceivable basis that might support the government’s action. (Doc. No. 350.)

In March 2024, just weeks before the last scheduled trial date in this case, the defendants filed their third joint Motion to Dismiss Indictment, this time premised upon lack of subject matter jurisdiction. (Doc. No. 380.) The defendants argued generally that the charges against them could only be sustained through reliance on a federal regulation, 21 C.F.R. § 1306.04, “through permission conveyed by ‘*Chevron* deference’ when a statute is ambiguous.” (*Id.* at 3.) On the same day, the defendants filed a Motion to Continue Trial, arguing that the viability of the doctrine of *Chevron* deference (derived from *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)), was under consideration in two cases pending before the Supreme Court and that the Supreme Court’s resolution of these cases would be dispositive of whether the government could charge registered medical practitioners with a violation of the CSA. (Doc. No. 377.) The court granted the Motion to Stay, noting that whether either Supreme Court case would be “resolved in a way that would jeopardize the Government’s theory of the case [was] a matter of speculation” but that, in any event, the cases “plausibly implicate[d]” issues of agency authority that were raised in the defendants’ Motion to Dismiss.” (Doc. No. 382 at 1.) The court subsequently indicated that it would issue a new briefing schedule after the Supreme Court issued the anticipated

rulings. (Doc. No. 394.) Shortly thereafter, the government pursued an interlocutory appeal of certain pretrial evidentiary rulings by this court, which stayed further proceedings. (Doc. No. 397.)

On June 28, 2024, the Supreme Court decided *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). As the parties anticipated, *Loper Bright* discarded the doctrine of *Chevron* deference, under which federal courts deferred to a federal agency’s “permissible” interpretation of a statute that was “silent or ambiguous with respect to the specific issue at hand.” *Loper Bright*, 603 U.S. at 379–80 (internal quotation marks omitted). Now, under *Loper Bright*, “[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority,” as required by the Administrative Procedure Act. *Id.* at 412.

On February 20, 2025, the Sixth Circuit issued its ruling on the government’s interlocutory appeal and remanded the case back to this court. This court thereafter granted the defendants leave to file an amended motion to dismiss and set a briefing schedule. On March 20, 2025, the defendants filed their Amended Motion to Dismiss (Doc. No. 430), accompanied by a Memorandum of Law (Doc. No. 431).<sup>4</sup> The government has filed a Response in opposition to the motion (Doc. No. 434), and the defendants have filed a Reply (Doc. No. 436).

The thrust of the defendants’ argument is that they cannot be convicted for conspiring to violate 21 U.S.C. § 841(a) because “Congress did not make it a crime for pharmacies to fill facially valid prescriptions, so long as the pharmacies’ registrations were valid under State and Federal law.” (Doc. No. 341 at 4–5.) More specifically, they contend that the only way for the court to find that they engaged in criminal conduct is through relying on or cross-referencing a regulation, 21 C.F.R. § 1306.04, “through permission conveyed by now-defunct *Chevron* deference,” and that,

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<sup>4</sup> The court terminated the third Motion to Dismiss as superseded by the Amended Motion to Dismiss. (Doc. No. 433 at 2.)

because the Supreme Court has now overruled *Chevron*, the court cannot defer to the Attorney General's regulation purporting to interpret the statute. (Doc. No. 430 at 7.) Further, they contend that (1) the regulation exceeded the Attorney General's authority, insofar as it "superimpose[s] a conditional authorization for medical practitioners or pharmacists"; (2) the regulation is vague and ambiguous, not in compliance with the Administrative Procedure Act, and, therefore, null and void; and (3) the court, in accordance with *Loper Bright*, must independently interpret the statute and must conclude, based on the plain language of the statute, that they did not engage in criminal conduct. In sum, they maintain that Count I of the Indictment does not charge a cognizable federal offense. (Doc. No. 430 at 9.) They also assert that, "[b]y extension, because Counts Two–Six . . . incorporate the allegations of violating 21 C.F.R. § 1306.04 . . . , those counts likewise fail to charge a cognizable offense." (*Id.* at 9.) Finally, they argue that the statutes they are charged with violating are void for vagueness, once stripped of reliance on the unauthorized regulation.

The court is not persuaded by any of these arguments. It finds, as set forth below, that *Loper Bright* is not relevant in this case; the Supreme Court's holding in *United States v. Moore*, 423 U.S. 122 (1975), applies to pharmacists as well as physicians; a pharmacist may be convicted of violating § 841(a) if the government proves that the pharmacist knew that he was "acting in an unauthorized manner, or intend[ed] to do so," *United States v. Campbell*, No. 23-5298, 2025 WL 1000136, at \*2 (6th Cir. Apr. 3, 2025) (quoting *Ruan*, 597 U.S. at 454); and § 841(a) is not void for vagueness. Moreover, because the defendants' arguments in support of dismissal of Counts Two through Six depend on the success of their attempt to nullify Count One, those arguments fail as well.

## II. LEGAL STANDARD

The defendants assert that the Indictment fails to allege a cognizable federal crime against them and that the court therefore lacks subject matter jurisdiction. (Doc. No. 430 at 9.)

The federal district courts have jurisdiction over the prosecution “of all offenses against the laws of the United States.” 18 U.S.C. § 3231. A defendant may move to dismiss a defective indictment for “failure to state an offense.” Fed. R. Crim. P. 12(b)(3)(B)(v); *United States v. Teh*, 535 F.3d 511, 515 (6th Cir. 2008). On a motion to dismiss, the court must read the indictment “as a whole, accepting the factual allegations as true, and construing those allegations in a practical sense with all the necessary implications.” *United States v. McAuliffe*, 490 F.3d 526, 531 (6th Cir. 2007).

“Claims that a statute named in an indictment does not proscribe the alleged conduct are generally treated as claims that the indictment ‘fails to state an offense.’” *Teh*, 535 F.3d at 515; *see also United States v. Adesida*, 129 F.3d 846, 850 (6th Cir. 1997) (“If an indictment does not charge a cognizable federal offense, then a federal court lacks jurisdiction to try a defendant for violation of the offense.”). A challenge to the court’s subject matter jurisdiction may be raised at any time, Fed. R. Crim. P. 12(b)(2), and, “[o]nce raised, . . . must be addressed.” *VanderKodde v. Mary Jane M. Elliott, P.C.*, 951 F.3d 397, 407 (6th Cir. 2020) (Sutton, J., concurring).

The government, as an initial matter, argues that alleged “defects” in an Indictment do not deprive the court of the power to adjudicate a case. (Doc. No. 434 at 7–8 (citing *United States v. Cotton*, 535 U.S. 625 (2002); *United States v. Hobbs*, 953 F.3d 853 (6th Cir. 2020); and *United States v. Cor-Bon Custom Bullet Co.*, 287 F.3d 576 (6th Cir. 2002)).) In the cases on which the government relies, however, the courts rejected the defendants’ arguments that “the failure of an indictment to allege an element of an offense charged prevents a district court from having subject-matter jurisdiction.” *See, e.g., Cotton*, 535 U.S. at 631 (reaffirming that “indictment defects” do not “deprive[] a court of jurisdiction”); *Hobbs*, 953 F.3d at 856 (rejecting defendant’s argument to

the contrary and holding that the indictment’s failure to allege the defendant’s knowledge that he was a previously convicted felon did not deprive the court of subject matter jurisdiction).

The defendants here do not move for dismissal based on mere “defects” in the Indictment. Instead, their position is that, even assuming that the Indictment sets forth all of the elements of the offenses charged and, further, that the defendants engaged in the conduct as charged, their conduct does not qualify as criminal conduct under the statutes as properly construed. The court finds that they have asserted a jurisdictional challenge and not merely a challenge to the sufficiency of the Indictment. In other words, merely restating the Indictment to allege additional facts would not, in the defendants’ view, cure the problem.

### III. ANALYSIS

#### A. Count One

##### 1. *Section 841(a)*

Count One of the Indictment charges the defendants with conspiring, in violation of 21 U.S.C. § 846, to “knowingly and intentionally and without lawful authority distribute and dispense and cause to be distributed and dispensed a mixture and substance containing a detectable amount of . . . controlled substances, not for a legitimate medical purpose and outside the usual course of professional practice,” including specified Schedule II, III, and IV controlled substances, “in violation Title 21, United States Code, Section 841(a)(1).” (Doc. No. 3 ¶ 39.)<sup>5</sup>

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<sup>5</sup> According the government’s Trial Brief, filed prior to one of the previously set trial dates for this matter, the two pharmacies at issue here—which were owned and operated by the defendants—dispensed “huge quantities” of Schedule II, III, and IV controlled substances between 2014 and 2019 to “patients defendants knew were abusing and diverting the drugs,” and, despite being “repeatedly warned that their conducted violated state and federal law,” the defendants kept “filling and billing for these prescriptions” for years. (Doc. No. 354 at 2.)

Under § 841, distribution and dispensing of controlled substances is unlawful “[e]xcept as authorized by this subchapter.” 21 U.S.C. § 841(a)(1). The CSA provides that “[p]ersons registered . . . under this subchapter to . . . distribute, or dispense controlled substances are authorized to possess, . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.” *Id.* § 822(b). The statute defines “practitioner” to include:

a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . , to distribute [or] dispense . . . a controlled substance in the course of professional practice . . . .

*Id.* § 802(21). In other words, § 841(a) “make[s] it unlawful to distribute a controlled substance knowingly or intentionally,” but “[t]he prohibition does not apply to pharmacists as long as their actions fall within the usual course of professional practice.” *United States v. Noel*, No. 20-6167, 2021 WL 5180915, at \*4 (6th Cir. Nov. 8, 2021) (citing 21 U.S.C. § 841(a)(1) and *Moore*, 423 U.S. at 124). “A pharmacist thus violates this drug-distribution prohibition if he knowingly fills a controlled substance prescription issued outside professional norms.” *Id.* (citing *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994)).

As the Indictment explains, the regulations implementing the CSA articulate the boundaries of that authority. Under 21 C.F.R. § 1306.06, “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy.” (*See also* Doc. No. 3 ¶ 6.) In addition, as set forth in 21 C.F.R. § 1306.04:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of



professional treatment . . . is not a prescription within the meaning and intent of section 309 of the [CSA] (21 U.S.C. [§] 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a). (*See also* Doc. No. 3 ¶ 5.)

The Sixth Circuit has repeatedly held that pharmacists can be convicted under § 841(a) if they fill prescriptions for controlled substances while “knowing that the prescriptions were outside the scope of professional practice and that they were not for a legitimate medical purpose.” *United States v. Jones*, 825 F. App’x 335, 339 (6th Cir. 2020); *see also, e.g., Noel*, 2021 WL 5180915, at \*4; *Veal*, 23 F.3d at 987–88; *United States v. Hughes*, 895 F.2d 1135, 1143 n.11 (6th Cir. 1990).

## 2. *The Defendants’ Position*

Despite the weight of this authority, the defendants insist that “Congress did not make it a crime for pharmacies to fill facially valid prescriptions, so long as the pharmacies’ registrations were valid under State and Federal law.” (Doc. No. 431 at 4–5.) To reach this conclusion, their argument goes something like this.

First, according to the defendants, the only way for a licensed pharmacist to be convicted under § 841(a) is if the language of a regulation, 21 C.F.R. § 1306.04, is “graft[ed] onto the elements of the offense.” (*Id.* at 6.) The defendants object in particular to the regulatory language that places on a pharmacist filling a prescription an “undefined ‘*corresponding responsibility*’ . . . to ensure that prescriptions written by licensed physicians or other practitioners are ‘medically necessary’ and issued in the practitioner’s ‘usual course of professional practice.’” (Doc. No. 431 at 6 (emphasis added).) The defendants construe this language to mean that pharmacists would be required to “engage in statistical analysis to determine whether in the aggregate prescriptions have” a sufficient number of “red flags” that the pharmacists can be criminally prosecuted for filling them. (*Id.* at 3, 4, 5 n.2.)

Next, according to the defendants, the regulation (thus construed) “expand[s] the elements of the criminal offenses to encompass conduct Congress did not criminalize by the terms of the statute,” as a result of which “subject matter jurisdiction is lacking.” (*Id.* at 6.) Citing *Loper Bright*, the defendants insist that the court may not simply defer to the Attorney General’s interpretation of the statute and is instead “empower[ed] . . . to dismiss the Indictment upon a comparison of the agency action to the terms of the statutes under which the defendants are charged.” (*Id.* at 6–7.) They concede that *Loper Bright* did not “entirely unravel[] the regulations at issue to the extent they do nothing more than restate the terms of the [CSA].” (*Id.* at 7.) They maintain, however, that, in this case, the regulation—and the Indictment—“criminalize conduct that is beyond the reach” of the CSA and, consequently, that the regulation is not entitled to deference and the Indictment must be dismissed for lack of subject matter jurisdiction. (*Id.*)

The defendants recognize that, in *United States v. Moore*, the Supreme Court was confronted with a virtually identical argument—that the statute itself did not apply to physicians “authorized” under the statutory scheme to prescribe controlled substances— and nonetheless upheld a physician’s conviction under § 841(a). *See Moore*, 423 U.S. at 129–30, 131–32 (rejecting the appellate court’s determination that “Congress intended to deal with registrants primarily through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties provided for in § 841 for those seeking to avoid regulation entirely by not registering”).

The defendants also acknowledge (*see* Doc. No. 431 at 9 n.4) that this court recently rejected a very similar motion to dismiss an indictment filed by two prescribing practitioners who, like the defendants here, argued that, because they were duly licensed and “authorized” to dispense prescriptions for controlled substances, they could not be prosecuted under § 841(a), or, by

extension § 846, based on the unambiguous language of the statute. Like the defendants here, they argued that the CSA did not authorize the Attorney General to adopt 21 C.F.R. § 1306.04 and that, even if the Attorney General had such authority, the agency’s definition of the terms used in the regulation was not entitled to any deference. In denying that motion, this court held that the defendants’ position was entirely foreclosed by *Moore*, which held—without relying on, or even referring to, the language of the regulation—that “doctors who engaged in illegitimate prescribing practices could be prosecuted under § 841.” *United States v. Marks*, No. 2:19-cr-00003, slip op. at 18 (M.D. Tenn. Feb. 14, 2025) (citing *Moore*, 423 U.S. at 139).<sup>6</sup>

As this court noted in *Marks*, the Supreme Court in *Moore* acknowledged that the CSA did not “spell out this limitation in unambiguous terms.” *Id.* (quoting *Moore*, 423 U.S. at 139). The Supreme Court nonetheless concluded, based on a common sense reading of the statute in light of its legislative history, that the term “authorized,” as used in § 841(a), “incorporate[d] a requirement that the prescribing practice by a registered practitioner be within the course of his professional practice.” *Id.* at 19. Because *Moore* did not rely on the language of the regulation to affirm the conviction at issue, this court found that the case was not implicitly overruled by *Loper Bright* or any other Supreme Court decisions that may have “progressively hint[ed] at limiting the authority of federal agencies.” *Id.* at 20. Instead, the court found that *Moore* was “nearly precisely on point and constitute[d] binding authority as to whether 21 U.S.C. § 841 charges a cognizable offense and as to how the term ‘authorized’ as used in § 841(a) should be interpreted.” *Id.*

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<sup>6</sup> Although the court expects the defendants to appeal that ruling, the criminal charges against them have not been adjudicated and the case is still pending in this court. However, Judge John Fowlkes, Jr. of the U.S. District Court for the Western District of Tennessee denied a nearly identical motion to dismiss for lack of subject matter jurisdiction in April 2024, also based on *Moore*. *United States v. Young*, 1:19-cr-100040-JTF (W.D. Tenn. April 4, 2024), ECF No. 341. The defendant in that case has been convicted, and his appeal is now pending in the Sixth Circuit. *United States v. Young*, No. 24-5430 (6th Cir.).

The defendants here, attempting to distinguish their situation from that of the physician defendants in *Marks* and *Moore*, contend that, “in stark contrast to *Moore*, courts considering pharmacy cases overtly and consistently rely on 21 C.F.R. § 1306.04 to interpret 21 U.S.C. § 841 as it applies to pharmacists filling prescriptions for controlled substances.” (Doc. No. 431 at 9 n.4.) And the Indictment in this case also quotes and relies on the regulation. (*See* Doc. No. 3 ¶ 5.) The defendants characterize the holding in *Moore* as

hing[ing] on a finding based on statutory language, that is, that Dr. Moore’s conduct “exceeded the bounds of ‘professional practice’”—not on whether there was a “medical necessity” for the methadone he prescribed. Implicit in the *Moore* opinion, therefore, is the limited reach of 21 U.S.C. § 841(a) to practitioners who prescribe or dispense medications outside the bounds of the professional standards of the practitioner’s State of licensure.

(Doc. No. 431 at 12 (quoting *Moore*, 423 U.S. at 142–43.)

The defendants further argue that *Moore* is not the Supreme Court’s “last word on jurisdiction to prosecute medical practitioners, pharmacists, or those alleged to have conspired with them to dispense controlled substances.” (Doc. No. 431 at 9.) They contend that *Moore*’s “precedential value,” particularly for the purpose of prosecuting pharmacists, has been “substantially diminished in the nearly 50 years since it was decided,” specifically by *Gonzales v. Oregon*, 546 U.S. 243 (2006).<sup>7</sup> From *Gonzales*’ holding that the Attorney General was not authorized to define the parameters of medical standards or to “make a rule declaring illegitimate

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<sup>7</sup> In *Gonzales*, the Court struck down an Interpretive Rule issued by the Attorney General that purported to interpret the term “legitimate medical purpose,” as used in 21 C.F.R. § 1306.04(a). More specifically, the Interpretive Rule prohibited dispensing controlled substances for use in physician-assisted suicide, based on the Attorney General’s decision that assisting a suicide could not to be a “legitimate medical purpose.” The Attorney General’s interpretation conflicted with Oregon law permitting physician-assisted suicide. The Supreme Court struck down the Interpretive Rule because it exceeded the Attorney General’s delegated authority under the CSA. *Gonzales*, 546 U.S. at 267.

a medical standard for care and treatment of patients that is specifically authorized under state law, *Gonzales*, 546 U.S. at 258, the defendants leap to the conclusion that,

[b]y extension, the Attorney General surely has no authority to make rules defining the parameters of a pharmacist's 'corresponding responsibility' to adhere to a physician's medical standards, particularly where a pharmacist has no corresponding access to a patient's medical records or the physician's professional experience of treating the patient, whether it be over one visit or multiple visits over a period of years.

(Doc. No. 431 at 15.)

### 3. Discussion

The defendants, in other words, are arguing that *Moore* does not save the Indictment as to them because the defendant there was a physician, not a pharmacist, and the Court was not obligated to refer to the regulation to conclude that a physician could be convicted under the statute. They argue that *pharmacists* cannot be convicted of violating § 841(a) unless the statute is deemed to be modified by the regulation, but the regulation exceeds the authority granted to the Attorney General by Congress and criminalizes conduct outside the scope of the statute itself, in contravention of both *Gonzales* and *Loper Bright*. The court, however, finds the defendants' efforts to distance themselves from *Moore*, to distinguish pharmacists from physicians, to somehow extract support for their position from *Gonzales*, and generally to extend *Loper Bright* to this case are all unavailing.

First, regarding the defendants' argument that *Gonzales* somehow confirms their position, the court finds that *Gonzales* has little bearing here, as it "dealt only with the question of the Attorney General's ability to define 'legitimate medical purpose' in light of state medical standards to the contrary," "was decided in the setting of administrative law, not criminal law," and "did not impose new requirements to prove a violation of the CSA." *United States v. Volkman*, 797 F.3d 377, 385, 386 (6th Cir. 2015).

*Gonzales* also does not support the defendants’ argument that 21 C.F.R. § 1306.04(a) exceeds the Attorney General’s authority. To the contrary, the *Gonzales* Court’s description of the regulation strongly suggests that it does not constitute an unlawful extension of the agency’s statutory authority. The Court described § 1306.04(a) as simply “repeat[ing],” “summariz[ing],” or “parroting” the statutes it implements. *Gonzales*, 546 U.S. at 257; *see also United States v. Lamartiniere*, 100 F.4th 625, 638 (5th Cir. 2024) (rejecting similar challenge and noting that, “[i]n *Gonzales v. Oregon*, the Supreme Court characterized § 1306.04(a) as ‘a parroting regulation’ because it ‘just repeats two statutory phrases [from the CSA] and attempts to summarize the others’” (footnoted citations omitted)), *cert. denied sub nom. Lamartiniere v. United States*, 145 S. Ct. 1069 (Jan. 13, 2025). A regulation that simply reiterates or paraphrases a statute is unlikely to exceed the authority granted the agency by Congress since, by definition, it is not extending the statute under which the agency purports to act, and a court that references such a regulation is not ceding to the implementing agency the court’s own responsibility to construe the statute.

In *Moore*, the Court interpreted the statute as “limit[ing] a registered physician’s dispensing authority to the course of his ‘professional practice.’” *Moore*, 423 U.S. at 140–41. Although the defendant in that case was a physician, nothing in the opinion suggests that its holding would not apply equally to pharmacists and other “practitioners” whose ability to prescribe or “dispense” controlled substances depends on their registration and whose registration presumes a certain standard of professional conduct. The Sixth Circuit has expressly recognized as much. *See Noel*, 2021 WL 5180915, at \*4 (citing *Moore* in support of the proposition that § 841 “does not apply to pharmacists as long as their actions fall within the usual course of professional practice”).

Further, the defendants’ efforts to hang their hat on the regulation’s use of the phrase “corresponding responsibility,” their depiction of that responsibility as requiring a pharmacist to

perform a statistical analysis every time he is called upon to fill a controlled substance prescription, and their repeated assertions that the government seeks to prove the defendants' culpability based simply on the pharmacists' filling prescriptions that were not "medically necessary" miss the mark. The term "medically necessary" appears nowhere in Count One of the Indictment or in § 1306.04(a), and, as set forth above, the Sixth Circuit has clearly defined the parameters of what the government must prove to convict a duly registered and licensed pharmacist under § 841(a): "A pharmacist thus violates this drug-distribution prohibition if he knowingly fills a controlled substance prescription issued outside professional norms." *Noel*, 2021 WL 5180915, at \*4 (citing *Veal*, 23 F.3d at 988); *see also Veal*, 23 F.3d at 987–88 ("As a registered pharmacist, Mr. Veal was entitled to dispense controlled substances in the usual course of his professional practice. To convict him on the drug distribution charges, therefore, the government was required to prove (a) that Mr. Veal filled prescriptions that were not issued for a legitimate medical purpose, and (b) that he did so knowing that the prescriptions were invalid." (citing *Hughes*, 895 F.2d at 1143 n.11)). In *Hughes*, the defendant expressly raised the same argument raised here—that, as a licensed pharmacist, he was "free to fill any facially valid prescription issued by a licensed physician." *Hughes*, 895 F.2d at 1143 n.11. The court rejected this argument "because of the substantial evidence indicating that [the defendant] knew that the prescriptions were not issued in the usual course of medical practice." *Id.*

None of these Sixth Circuit cases acknowledges or addresses the "corresponding responsibility" language contained in § 1306.04(a). Read in context, it seems clear that the sentence in which that phrase appears is modified and explained by the sentence following it: the pharmacist who "knowingly fills" a prescription that was not issued in the usual course of professional treatment violates the law. 21 U.S.C. § 1306.04(a). And this, of course, is how courts

have construed it. *See, e.g., United States v. Lovern*, 590 F.3d 1095, 1099 (10th Cir. 2009) (Gorsuch, J.) (“Accordingly, . . . the person knowingly filling such a purported prescription”—*i.e.*, one issued “not in the usual course of professional treatment”—“shall be subject to the penalties provided for violations of the [CSA].” (emphasis added) (internal citations and quotation marks omitted)). Thus, with respect to the defendants’ contention that this phrase violates *Gonzales* because it somehow purports to define which practices are or are not within the course of professional medical practice, *Gonzales*, again, simply does not apply. The court is not confronted with an interpretive rule that seeks to define a particular practice as lacking a legitimate medical purpose. Rather, the government will have to establish that the prescribing practices underlying the controlled substance prescriptions here were “inconsistent with the usual course of professional practice the old-fashioned way: through witnesses and documentary proof at trial focused on the contemporary norms of the medical profession.” *Id.* at 1100. And the defendants will be “free at all times to present contrary proof that [their] behavior and those of the . . . prescribing physicians were consistent with the usual course of professional practice. And, again unlike *Gonzales*, the jury [will remain] free to sort out all the competing proof: the question what constitutes usual medical practice remain[s], at all times, within its province.” *Id.*

Finally, as indicated above, the defendants themselves seem to recognize that, under *Moore*, pharmacists can be convicted of violating § 841(a) if they “dispense medications outside the bounds of the professional standards of the practitioner’s State of licensure.” (Doc. No. 431 at 12 (citing *Moore*, 423 U.S. at 142–43).) To the extent the language in § 1306.04(a) referring to a pharmacist’s “corresponding responsibility” could be construed as requiring something more—for instance, as requiring pharmacists to perform statistical analyses or to affirmatively establish the validity of every controlled substance prescription they fill—that would likely be a bridge too far.



But, insofar as the regulation read as a whole can be construed consistently with the statute to mean that pharmacists exceed their authority by filling prescriptions while *knowing* that they were issued outside the usual course of medical practice, the regulation does no more than, as the Supreme Court said, “parrot[]” the statute. *Gonzales*, 546 U.S. at 257.

The court, in sum, rejects the defendants’ argument that duly licensed pharmacists cannot be convicted of violating § 841(a) and, *ipso facto*, that the defendants cannot be convicted under § 846 of conspiring with the pharmacists to violate § 841(a). The regulation and the statutory scheme together have been consistently construed, since *Moore*, to prohibit pharmacists (and other dispensing practitioners) from filling prescriptions that they know are invalid. *Loper Bright* is irrelevant here, and the court remains bound by *Moore* and subsequent Sixth Circuit cases applying *Moore*’s holding to pharmacists’ convictions under § 841.

## **B. Counts Two Through Six**

Count Two charges the three defendants with conspiring to knowingly and willfully execute a scheme to defraud a government health care benefit program (“GHCBP”) (specifically Medicare and TennCare). In support of this charge, the government alleges that Dale Hollow Pharmacy, through Thomas Weir and Charles Oakley, and Xpress Pharmacy, through Thomas Weir and Pamela Spivey, maintained enrollment in the GHCBPs and certified, through the defendants, that the pharmacies would comply with all Medicare and Medicaid rules and regulations and other federal laws, including the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and would not knowingly present or cause to be presented a false and fraudulent claim for payment by a GHCBP. (Doc. No. 3 ¶¶ 44, 47.) The government alleges that the defendants (and others with whom they conspired) knew that the GHCBPs “did not pay for dispensed medications that were invalid, not eligible for reimbursement, not provided as represented, and/or were medically unnecessary” but nonetheless dispensed, or caused to be dispensed, controlled substance

prescriptions that were invalid, not eligible for reimbursement, not provided as represented, and/or were medically unnecessary and submitted or caused others to submit claims for reimbursement to the GHCBPs. (*Id.* ¶¶ 48, 49.)

Counts Three and Four charge Weir and Spivey (aided and abetted by others) of health care fraud in connection with reimbursement claims for two specific controlled substance prescriptions filled for two different patients on specific dates in 2016 and 2017. (*Id.* ¶¶ 51–52.) Counts Five and Six charge Weir (aided and abetted by others) on two substantive counts of health care fraud in connection with reimbursement claims for two controlled substance prescriptions for a single patient, both dispensed on a single day in 2018. (*Id.* ¶¶ 54–55.)<sup>8</sup>

To prove a violation of § 1347, the government must prove that each defendant “(1) knowingly devised a scheme or artifice to defraud a health care benefit program in connection with the delivery of or payment for health care benefits, items, or services; (2) executed or attempted to execute this scheme or artifice to defraud; and (3) acted with intent to defraud.” *United States v. Anderson*, 67 F.4th 755, 770 (6th Cir. 2023) (quoting *United States v. Semrau*, 693 F.3d 510, 524 (6th Cir. 2012)), *cert. denied*, 144 S. Ct. 552 (2024). Fraudulent intent may be proved by circumstantial evidence, and a jury may “infer intent from evidence of efforts to conceal the unlawful activity, from misrepresentations, from proof of knowledge, and from profits.” *Id.* (quoting *United States v. Persaud*, 866 F.3d 371, 380 (6th Cir. 2017)). A defendant is guilty of

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<sup>8</sup> The government’s Trial Brief alleges that “[t]he patients identified in the indictment at Counts Three and Four filled combinations of controlled substances for years at the pharmacies despite repeated red flags. Xpress only stopped filling their prescriptions when both patients overdosed and died. The patient at Counts Five and Six had multiple prescribers and pharmacies between 2015 and 2018. Dale Hollow continued to fill dangerous combinations for this patient.” (Doc. No. 354 at 15 n.10.)

healthcare fraud if he “contributed to the execution of the scheme with intent to defraud.” *Id.* (quoting *United States v. Hunt*, 521 F.3d 636, 645 (6th Cir. 2008)).

To prove a conspiracy to commit health care fraud, the government must prove (1) the existence of an agreement to commit health care fraud, (2) the defendant’s “knowledge and intent to join the conspiracy,” and (3) “an overt act constituting actual participation in the conspiracy.” *United States v. Campbell*, No. 23-5298, 2025 WL 1000136, at \*7 (6th Cir. Apr. 3, 2025) (quoting *United States v. Hughes*, 505 F.3d 578, 593 (6th Cir. 2007)). To prove that a defendant conspired to commit health care fraud under Section 1349, the government must prove that “the defendant voluntarily made an agreement, ‘tacit or explicit,’ to knowingly defraud a health care benefit program.” *United States v. Williams*, 662 F. App’x 366, 372 (6th Cir. 2016) (quoting *United States v. Medlock*, 792 F.3d 700, 711 (6th Cir. 2015)). “Evidence of actual fraud against [a GHCBP] and a defendant’s knowledge thereof and benefit therefrom is sufficient proof to uphold a conviction under § 1349. *Id.* (citing *Medlock*, 792 F.3d at 711).

Here, the defendants assert that Counts Two through Six of the Indictment should be dismissed, because the government’s prosecution in this case “depends on federal regulations [that] improperly expand the reach of 18 U.S.C. §§ 1347 and 1349.” (Doc. No. 431 at 18.) More specifically, the defendants argue that, insofar as the government intends to rely on § 1306.04(a)’s “undefined ‘corresponding responsibility,’” that regulation is void under *Loper Bright* because it was “unlawfully created” and “ultimately stretches the health care fraud statutes beyond their jurisdictional contours.” (Doc. No. 431 at 19.) In other words, the defendants are arguing that they cannot be convicted of health care fraud based on a violation of § 1306.04, for the same reasons that they cannot be convicted of conspiring to violate § 841(a) based on the same regulation. This

argument, however, fails for the same reasons as the defendants' contention that they cannot be convicted for conspiring to violate § 841(a), discussed above.

Next, the defendants follow a tangled thread of interlocking Medicare regulations to reach the same argument again: that, ultimately, to establish that the defendants billed (or caused others to bill) Medicare “for controlled substances that were not ‘medically necessary’ and were therefore ‘false claims,’” “the Indictment bootstraps the allegations in Count One of conspiracy to dispense ‘medically unnecessary’ controlled substances, with specific reference to terms used (but not defined) in 21 C.F.R. § 1306.04 by incorporating into Counts 2–7 all of the allegations set forth in Count 1.” (Doc. No. 431 at 21 (citing Doc. No. 3 ¶¶ 40, 50, 53).<sup>9</sup>) They again argue that, “because *Gonzales* and *Loper Bright* compel a dismissal of Count One, Counts Two [through] Six must likewise be dismissed as they depend on the same discredited regulations.” (*Id.*) The court, again, rejects this argument for the same reasons it declines to dismiss Count One.

Moreover, Section 1347 is “a simple fraud statute.” *United States v. McLean*, 715 F.3d 129, 136 (4th Cir. 2013), *cited in United States v. Sisco*, No. 22-5202, 2023 WL 119398, at \*3 (6th Cir. Jan. 6, 2023). And the Sixth Circuit has repeatedly affirmed convictions under § 1347 (and related conspiracy convictions) based on the submission of claims for reimbursement for services that the defendants knew were not medically necessary. *See, e.g., Oppong v. United States*, No. 24-3246, 2025 WL 655542, at \*9 (6th Cir. Feb. 28, 2025) (finding sufficient evidence of health care fraud based on the defendant’s issuing “prescriptions allowing for multiple refills without any apparent medical necessity or patient exam”); *United States v. Bolos*, 104 F.4th 562, 573 (6th Cir.

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<sup>9</sup> These paragraphs of the Indictment, which are the first paragraphs that appear under the headings for Count Two, Counts Three and Four (which are charged in one section of the Indictment), and Counts Five and Six (likewise charged in a single section), set forth boilerplate language “incorporate[ing] by reference” all preceding paragraphs of the Indictment.

2024) (affirming the defendant’s mail fraud and health care fraud convictions and observing that “there is a consistent history of [health care fraud] convictions for the billing of unnecessary medicines and procedures, which is analogous to the fraud here”(collecting cases)); *Anderson*, 67 F.4th at 763, 770–71 (affirming CSA and health care fraud conviction based in part on expert testimony that “Medicare would not pay for services or medications it knew were medically unnecessary or were prescribed in violation of state or federal law”); *United States v. Bertram*, 900 F.3d 743, 751–52 (6th Cir. 2018) (affirming conviction based on (“ample evidence to conclude that the defendants knew the [urine drug] tests were medically unnecessary and that billing for them was illegal”); *United States v. Agbebiyi*, 575 F. App’x. 624, 625 (6th Cir. 2014) (“Medicare claims must be for services which are medically necessary. Providers are responsible for knowing the Medicare rules and regulations, and for submitting claims in accordance with those regulations.”). The Sixth Circuit has, in fact, referred to “claims for pharmaceuticals or supplies in the obvious absence of medical need” as “the paradigm health care fraud case.” *United States v. Davis*, 490 F.3d 541, 547 (6th Cir. 2007). Although many of these cases rely on the same evidence to affirm convictions for both CSA and health care fraud convictions, *see, e.g., Anderson*, 67 F.4th at 769, 771, the government does not necessarily have to prove a violation of § 841(a), or to incorporate by reference 21 C.F.R. § 1306.04, to prove health care fraud based on the knowing submission of claims that lacked medical necessity.

The defendants have not established that the health care fraud charges against them are invalid or subject to dismissal for lack of subject matter jurisdiction.

### **C. The Statutes Are Not Void for Vagueness**

Finally, the defendants argue that the statutes on which the criminal charges against them are premised, including both 21 U.S.C. § 841(a) and 18 U.S.C. § 1347, once stripped of reliance on 21 C.F.R. § 1306.04(a)), are unconstitutionally vague. Because the court has found the central

premise upon which this conclusion relies is without merit, it logically follows that the conclusion is also without merit.

Regardless, the statutes are not void for vagueness. Generally, “the void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.” *Risbridger v. Connelly*, 275 F.3d 565, 572 (6th Cir. 2002) (quoting *Kolender v. Lawson*, 461 U.S. 352, 357 (1983)). Thus, “[v]agueness may invalidate a criminal statute if it either (1) fails ‘to provide the kind of notice that will enable ordinary people to understand what conduct it prohibits’ or (2) authorizes or encourages ‘arbitrary and discriminatory enforcement.’” *United States v. Caseer*, 399 F.3d 828, 836 (6th Cir. 2005) (quoting *United States v. Bowker*, 372 F.3d 365, 380 (6th Cir. 2004)).

The Supreme Court has “recognized that the requirement of a specific intent to do a prohibited act may avoid those consequences to the accused which may otherwise render a vague or indefinite statute invalid.” *Screws v. United States*, 325 U.S. 91, 101 (1945). More to the point, “where the punishment imposed is only for an act knowingly done with the purpose of doing that which the statute prohibits, the accused cannot be said to suffer from lack of warning or knowledge that the act which he does is a violation of law.” *Id.* at 102. In light of this principle, courts have uniformly held that the *mens rea* requirement for § 1347 convictions “mitigates any ambiguity arising from the lack of clear medical guidance.” *McLean*, 715 F.3d at 136–37 (citing *United States v. Jaensch*, 665 F.3d 83, 90 (4th Cir. 2011)); see also *United States v. Franklin–El*, 554 F.3d 903, 910–11 (10th Cir. 2009) (rejecting a vagueness challenge to § 1347 premised on the complexity of Medicaid regulations because the statute is “simply a fraud statute”).

Likewise, the CSA contains a strict scienter requirement, which also serves to mitigate whatever potential ambiguity might arise from the statute's (and regulations') lack of guidance as to what conduct is consistent with a "usual course of professional practice." As the Sixth Circuit has explained,

to prove a conspiracy to unlawfully distribute, the government must prove beyond a reasonable doubt that the defendant "knowingly and voluntarily joined" an "agreement" to violate Section 841. And after *Ruan*, a person cannot "knowingly" agree to violate § 841 unless he agrees to commit acts he *knows* are unauthorized. Thus, the government cannot prove a § 846 violation unless it proves that the conspirators in the agreement knew they were acting—or intended to act—without a legitimate medical purpose in the usual course of professional practice.

*Campbell*, 2025 WL 1000136, at \*2 (internal citations omitted) (citing *Ruan* 597 U.S. at 545).

In any event, despite the Supreme Court's having recognized that the CSA and the implementing regulations are ambiguous, the Sixth Circuit and numerous other circuits have rejected similar void-for-vagueness arguments. *See, e.g., United States v. DeBoer*, 966 F.2d 1066, 1068–69 (6th Cir. 1992) (rejecting the pharmacist defendant's void-for-vagueness challenge to his conviction under § 841(a), because "the language in § 841(a)(1) and 21 C.F.R. § 1306.04(a) clearly defines the pharmacist's responsibilities that give rise to conduct that constitutes an unlawful distribution of a prescription drug," and "there was sufficient evidence in the record to prove that the defendant acted outside the scope of his profession"); *accord United States v. Orta-Rosario*, 469 F. App'x 140, 143 (4th Cir. 2012) (rejecting void-for-vagueness challenge premised upon the argument that the CSA contained "no statutory definition of 'legitimate medical purpose' or 'usual professional practice,'" concluding "[i]n light of the statute, regulation, and case law . . . that the Defendants had adequate notice that [their conduct] was unlawful"); *United States v. Birbragher*, 603 F.3d 478 (8th Cir.2010) (rejecting vagueness challenge in online pharmacy case).

In *Lovern*, then-Judge Gorsuch rejected the defendant pharmacist's similar void-for-vagueness challenge, noting that, outside the First Amendment context, such a challenge "must be

examined in light of the facts of the case at hand.” *Lovern*, 90 F.3d at 1103 (quoting *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 495 n.7 (1982)). Judge Gorsuch, writing for the Tenth Circuit, found that the evidence presented in that case

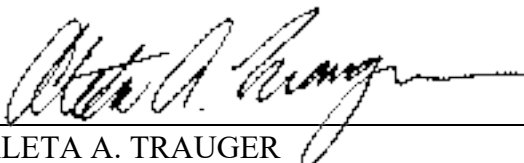
demonstrate[d] that [Mr. Lovern] had knowledge of the illegality of his activities, and thus this is not a situation where he could not reasonably understand that his contemplated conduct is proscribed. Mr. Lovern was a pharmacist with decades of experience. According to his own testimony, Mr. Lovern understood that he had a legal duty to ensure he filled only those prescriptions issued in the usual course of medical practice. He understood as well that a patient-physician relationship, including a physical examination, usually precedes a prescription in contemporary medical practice. And he knew that the prescriptions he filled at Red Mesa were issued after a customer filled in an online questionnaire with no follow-up physical examination or consultation with a physician. A reasonable jury could find that Mr. Lovern knowingly filled prescriptions issued outside the usual course of medical practice, something Mr. Lovern admitted he could not do lawfully.

*Id.* Based on this evidence, the court concluded that it “could not say” that the defendant “was the unwitting victim of a law he didn’t understand.” *Id.*

This case has not yet gone to trial, and it remains to be seen both what evidence the government will present and whether the jury will find that evidence sufficient to prove beyond a reasonable doubt that any defendant is guilty as charged. But, from this pretrial vantage point, in light of Sixth Circuit precedent and other persuasive authority, the court finds that the defendants have failed to establish that the statutes under which they are charged are void for vagueness.

#### IV. CONCLUSION

For the reasons set forth herein, the defendants’ Amended Motion to Dismiss Counts One–Six of the Indictment (Doc. No. 430) will be denied. An appropriate Order is filed herewith.

  
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ALETA A. TRAUGER  
United States District Judge